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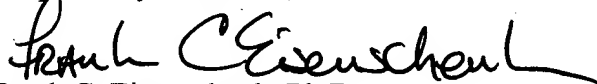
Remarks

Applicant respectfully requests entry of this preliminary amendment. Support for the claim amendments and amendments to the specification may be found in the priority document at pages 10, 11, 14-16, 59, 64-65, and 77 and in the subject specification at pages 14-19, 24-25, 38-43. The undersigned submits that no new matter has been added.

In view of the foregoing remarks and the amendments to the claims, the applicant believes that the pending claims are now in condition for allowance, and such action is respectfully requested. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments: Marked-Up Version of Amended Specification
Marked-Up Version of Table I
Replacement Table I pages
Fee Transmittal Form (in triplicate)
Transmittal Form

Marked-Up Version of Amended SpecificationCase 2Anaphylaxis to Renal Dialysis

An adult patient (age 16) had rejected three kidney transplants and was on dialysis. She had severe anaphylaxis to renal dialysis. Initial therapy involves administration of 4-5 capsules daily of L amino acids according to the invention, each capsule containing 390 to 500 mgm essential amino acids in L form and essential lipids. The therapeutic formulation comprises linoleic and linolenic fatty acid for a total amount of about 0.3 to 0.5 g per day, the antioxidant lipid EPA at about 0.3 to 0.5 gram per day, DHA at about 240 mgm per day, and extracellular matrix materials ~~chondroitin~~chondroitin sulfate, cartilage, and collagen in a total amount of about 1500 mgm per day. The patient ~~was~~is able to use reduced levels of antirejection medication (such as corticoids, macrolides, and cyclosporin) and thereby reduce the onerous side effects from these medications.

The therapy can also be administered before, during, and after renal transplant to aid in preventing organ rejection.

Case 7Chronic Inflammatory Bowel Disease (Regional Ileitis)

A 68 year-old female patient ~~is~~was diagnosed with Crohn's disease (also known as regional ileitis). The diagnosis was made by small bowel barium x-ray. Diagnosis had also been made by surgical removal of seven inches of terminal ileum twenty years ago. The patient received Neocate™ in the form of five capsules containing 390 milligrams each three times a day. This was preceded by a course of 155 milligrams of omega 3 eicosapentanoic acid lipid and 125 mgm DHA administered three times a week for two weeks. The patient had an excellent response with no symptom flare-ups, the absence of side effects attributable to the therapy, and the ability to avoid increasing the dosage of corticosteroids. The patient continued to receive triamcinolone acetate 4 milligrams daily before, during, and after the inventive therapy. In contrast, the patient had needed triamcinolone acetate dosage increases as frequently as every

three to four weeks before the inventive therapy was administered. After treatment with the inventive therapy, the patient was able to reduce her average daily corticosteroid dosage by one half. Furthermore, flare-ups were reduced. Thus, the severity of corticosteroid side-effects, such as ecchymoses and bruising, were greatly minimized. The unpleasant taste of the therapeutic compositions was overcome by formulating as capsules. Before meals, 5 capsules of the therapeutic formulation ~~are~~were ingested to allow relief from the extreme discomfort resulting from ingesting dairy products and beef.

Case 8

The patient of Case 7 ~~has~~had the commonly seen complications of long term corticosteroid use, such as recurrent and excessive bruising, particularly of the arms and hands, and difficulty of healing from the mildest trauma. Additional therapy of vitamin K (Mephyton 5 mgm) 4 tablets daily was prescribed. An ointment of Neocate (390 mgm), zinc oxide and vitamin E was prepared, and applied topically to bruises daily with a pressure dressing on any lacerations to accelerate healing.

Case 10

Pericardial Effusion

A 70-year old male ~~is~~was diagnosed by cardiac ultrasound and chest x-ray with pericardial effusion (an autoimmune reaction). He ~~is~~was prescribed a three week regime of the antibiotic Biaxin (500 mg tablet twice daily for persistent bronchitis, Abbott Laboratories, Chicago, IL). He ~~is~~was also diagnosed with a false lupus autoimmune reaction to the antibiotic. The Ppatient ~~is~~was removed from all other medications and receiveds the following therapy: cartilage, 2,220 mg capsules daily divided equally to 740 mg taken three times daily; EPA, 360 mg capsules once daily; and omega 3 antiinflammatory fatty acids. In three weeks, his fever and fatigue lessened. His blood sedimentation rate improved dramatically from 75 mm per hour to a normal of 15. His antinuclear antibody (ANA) titer also greatly improved to 1 dilution titer above normal (1:320). His chest x-ray showed no pericardial effusion.

Case 11Arthritis

A female patient age 45 ~~is~~was diagnosed with traumatic arthritis of the left knee. No response ~~is~~was shown to non-steroidal anti-inflammatory medications. For a limp associated with the arthritis, she ~~is~~was prescribed 740 mg capsules three times daily of chondroitin sulfate collagen cartilage (shark source). After several months of therapy, she ~~is~~has greatly improved and almost free of symptoms. Her chronic bronchitis (which had not responded to a three to four week course of antibiotics) greatly improved in 1-2 days and cleared in one or two weeks when the cartilage dosage described in this case was tripled.

TABLE I - Marked-Up Version

Amino Acids	Tissue Healing	Immune System A-B-Antibody (Ab) Formation	Cell Function DNA RNA Genetics	Skin Texture	Cancer	AIDS	Drug Addiction Amino Acid Deficiency	CNS	Neuro Transmitte	Antiangiogenic Anabolic Growth
L Lysine	++	+ Ab-&-B								++
L Glutamate										++
L Leucine	++			+					+	+++
L Proline	+			+						++
L Arginine	+++	+ Ab-B + Immune System		++	+	+				+++
L Valine	++						+			++
L Isoleucine	++							+		++
L Aspartic Acid		+ Ab-B + Immune System	+ sprouts seeds					+		++
L Asparagine									+	
L Glycine	+		+	+				+		++
L Threonine	+	+ Immune System		+						++
L Tyrosine	+						+			+
L Phenylalanine								++	+	++
L Serine		+ AbB + Immune System		+		+		++		+++
L Histidine	+++		+			+		+		+++
L Alanine								++		
L Tryptophan								+	+	+++
L Methionine		++	+	+				++		++
L Glutamine	+				+			+		++
Taurine		++	+							++
L Carnitine										+
L Cystine	+		+	+				+		+
L Cysteine	+			+						+

TABLE I – Marked-Up Version (cont'd)

Amino Acids	Liver	Ammonia- Removal & Toxins	G.I. Inflammatory Bowel Disease	Sports Muscle Fatigue Anti- Fatigue	Heart & Cardio- Vascular	Red Blood Cells	Endocrine Hormone	Enzyme Production	Arthritis Control	Storage (Fat)	The Control of Blood Sugar	Protein Synthesis	Pos. Nitrogen Balance	Toxic Compounds	Associated/ Inter-Related Vitamin Use	Radiation Damage Protection
L Lysine				+			+	+		+		+	+			
L Glutamate	+	+									+					
L Leucine		+		++			+								+	
L Proline				+	+				+							
L Arginine	+						+	+	+	+		+	++			
L Valine				++							+		++			
L Isoleucine				++		+				+						
L Aspartic Acid	+	+		+												
L Asparagine																
L Glycine				+												
L Threonine	+			+							+					
L Tyrosine							+									
L Phenylalanine									+							
L Serine				+						+			++			
L Histidine									+				++	+		
L Alanine											+		++			
L Tryptophan					+		+									
L Methionine	+			+	+					+				+		
L Glutamine	+		+	+					+		+				+	
Taurine				+	+					+						
L Carnitine	+			+						+	+					
L Cystine	+			+											+	
L Cysteine															+	+